REMARKS

The Applicants appreciate the Examiner's thorough examination of the subject application. Applicants request reconsideration of the subject application based on the following remarks.

Claims 32-36, 38-44, and 52-53 are pending in the application. Claims 1-31, 37, and 45-51 have been cancelled. Claims 32-36, 38, 39, 42, and 52 have been amended to more clearly define the invention. Support can be found at least in the claims as originally filed. No new matter has been introduced by the instant amendments.

Claims 32-36, 38-44 and 52-53 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention of record. It is further alleged that the specification does not reasonably provide enablement for the treatment of diseases caused by injuries to nervous tissues or the spinal cord.

The Office Action misinterprets the subject matter of the invention. At page 2, line 6 of the last paragraph, the Office Action states that "the specification, while enabling a method of inducing apoptosis or apoptosis-like cell death of oligodendrocytes comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1, ..."

The claimed invention provides methods of treating traumatic and/or compressive injuries to nervous tissue of a patient by administering a therapeutically effective amount of a pharmaceutical composition comprising a ginsenoside Rb_1, its metabolites or salt thereof. The dosage of ginsenoside ameliorates the damage caused by the injury by ***preventing*** cell death in the injured nervous tissue.

Enabling disclosure supporting the instant claims can be found throughout the spefication. In particular, the specification provides preferred dosage amounts to obtain the desired therapeutic effect in human patients. See, for example page 30, line 17 to page 31, line 10 which provide that a therapeutically effective amount of the ginsenoside Rb_1 for human patients with cerebral apoplexy is between about 1.2 mg/day to 12 mg/day for a 60 kg human patient. Suitable therapeutically effective amounts for other diseases or disorders caused by damage to nervous tissues can be readily calculated from rat models and/or the dosages for cerebral apoplexy.

Under the heading titled "Response to Arguments" the Examiner averred that the specification is limited to the effect of ginsenoside Rb_1 on rats with spinal cord injuries. Applicants respectfully disagree. Rats are known in the art to successfully model human therapeutic applications for spinal cord injuries. See, for example, D. L. Behrmann, et al., "Modeling of Acute Spinal Cord Injury in the Rat: Neuroproteciton and Enhanced Recovery with Methylperdnisolone, U-74006F and YM014673" *Experimental Neurology*, **126**, 61-75 (1994), a copy of which is provided in Appendix A.

The Behrmann publication provides an illustrative example of controlled spinal cord injury in rats being used as a model for testing therapeutic agents efficacy in humans. Thus, the instant specification provides ample written description of the claimed invention for one of ordinary skill in the art to understand and practice the instant invention.

Additional support can be found at least in the specification as originally filed, in Example 4, which demonstrates the effect of ginsenoside Rb_1 for the treatment of diseases caused by injuries to the spinal cord (a nervous tissue).

Example 4 demonstrates that anesthetized rats were subjected to spinal cord injury by compression loading. The vertebral arch was removed from the rats to expose

the spinal cord and the spinal cord injury was prepared by directly loading 20 g of compression for 20 min. Because the rats' weight is about 300 g, and 20 g of compression was applied, approximately 1/15 of the rats' weight was administered as the compression loading. This weight is comparable to 4 kg (~8.8 pounds) weight being loaded directly onto the exposed spinal cord of a human weighing 60 kg (~132.3 pounds).

The compression applied to the nervous tissues and spinal cord tissues resulted in the destruction of said tissues, and resulting neuroparalysis. Those of ordinary skill in the art are aware that the seriousness of these injuries are comparable to other models of neurotrauma, such as head injuries and brain injuries. Thus, Example 4 demonstrates a model of traumatic or compression injury to the nervous tissues.

When a saline solution was administered as a treatment, it was determined that the rat exhibited paraplegia in both hind limbs (Figure 8A). However, when a solution of ginsenoside Rb_1 was administered, the paraplegia of both hind limbs was significantly ameliorated (Figure 8B). Figure 8B demonstrates that the rat had the ability to stand up with the aid of a standing bar. Additionally, Figure 9 shows that the motor ability of the rats with spinal cord injuries was significantly ameliorated after administration of ginsenoside Rb_1.

Among neurotrauma, those of ordinary skill in the art are aware that spinal cord injuries are among the most difficult to treat. It is therefore determined that effective compounds for the treatment of serious spinal cord injuries can be expected to be effective on general neurotrauma, such as head injuries and peripheral nerve injuries.

Therefore, Applicants respectfully submit that the instant application provides sufficient enablement for the treatment of diseases caused by traumatic or compression injuries to nervous tissues, comprising the step of administering to a patient a therapeutically effective amount of a pharmaceutical composition comprising a therapeutic agent selected from ginsenoside Rb_1, its metabolites and salts thereof.

Applicants indicate that the rejection is thus obviated and respectfully request withdrawal of the rejection.

The Examiner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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